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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,970	12/13/2001	Marcus B. Gohlke	068349.0120	4120

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EXAMINER

COE, SUSAN D

ART UNIT PAPER NUMBER

1655

DATE MAILED: 12/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/021,970

Applicant(s)

GOHLKE, MARCUS B.

Examiner

Susan D. Coe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5,6,8,9,12-18 and 25-39 is/are pending in the application.
- 4a) Of the above claim(s) 25-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,6,8,9 and 12-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 7, 2005 has been entered.
2. Claims 2, 4, 7, 10, and 11 have been cancelled.
3. Claims 1, 3, 5, 6, 8, 9, 12-18 and 25-39 are currently pending.
4. Claims 25-39 have been withdrawn from consideration as being drawn to a non-elected invention.
5. Claims 1, 3, 5, 6, 8, 9, and 12-18 are examined on the merits. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

6. Claims 1, 3, 5, 6, 8, 9, and 12-17 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2002/0119928 for the reasons set forth in the previous Office action.

Applicant's arguments submitted August 18, 2005 have been considered. All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the reference does not anticipate the claimed invention because the reference does not teach the newly claimed limitations in regards to the ratios and weight percentages of the lactoferrin and beta-glucan. However, the reference teaches using lactoferrin in an amount of 0.642% (this is considered to fall within applicant's limitation of

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“about 0.7%”) and in amounts of 0.909 to 6.67% (0.909 is considered to fall within applicant’s limitation of “about 0.908”). The reference also specifically teaches using 0.001 to 10% of beta-glucan with 1.280% used in a specific example (see paragraphs 95 and 96). Thus, the amounts of beta-glucan and lactoferrin used fall within the amounts claimed by applicant. In addition, applicant’s claims use “comprising” language which does not exclude any additional elements including additional lactoferrin and beta-glucan.

Applicant also argues that the “underlying mechanism on which US ‘928 is based in contradictory (see page 11, lines 1 and 2 of the response).” However, the “mechanism” proposed by US ‘928 does not change the teaching of the reference of a composition that is structurally the same as the composition claimed by applicant. Thus, the reference properly anticipates the stated claims.

Claim Rejections - 35 USC § 103

7. Claims 1, 3, 5, 6, 8, 9, and 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/08960 (with US 6,306,453 as the English language equivalent) for the reasons set forth in the previous Office action.

Applicant’s arguments submitted August 18, 2005 have been considered. All of applicant’s arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the claimed invention is patentable over the reference because the reference does not specifically teach the claimed amounts of the ingredients. However, the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. “[W]here the general conditions of a

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claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

8. Claims 1, 3, 5, 6, 8, 9, and 12-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 6,241,983 in view of US Pat. No. 5,670,138 for the reasons set forth in the previous Office action.

Applicant's arguments submitted August 18, 2005 have been considered. All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the reference teaches away from using lactoferrin the amounts claimed by applicant because the reference teaches using lactoferrin at 0.0001 to 0.1 % rather than 0.25 to 0.908%. However, "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. Applicant has not established that the concentrations claimed produce unexpected results. Thus, since the reference does teach that the concentration of the

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components can be varied, any variation of ingredient amount is considered to be within routine experimentation unless unexpected results are demonstrated.

Applicant also argues that there is no motivation for combining US '138 with US '983. US '183 is used to demonstrate knowledge that would be available to anyone with skill in the art. Both references are drawn to oral products. Thus, the information provided by US '183 is properly combined with US '983.

9. Claims 1, 3, and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0119928 in view of US Pat. No. 5,670,138 for the reasons set forth in the previous Office action.

Applicant's arguments submitted August 18, 2005 have been considered. All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues against this rejection for the same reasons discussed in the above 102 rejection. Thus, this rejection is still considered valid for the reasons discussed above. IN addition, applicant argues that there is no motivation for combining US '138 with US '928. US '183 is used to demonstrate knowledge that would be available to anyone with skill in the art. Both references are drawn to oral products. Thus, the information provided by US '183 is properly combined with US '928.

10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 9:30 to 5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey, can be reached on (571) 272-0775. The official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding can be directed to the receptionist whose telephone number is (571) 272-1600.



Susan D. Coe
Primary Examiner
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